BACKGROUND

Informational Hearing

PROTECTING PUBLIC HEALTH: PREVENTING DISEASE THROUGH IMMUNIZATIONS

Tuesday, March 3, 2009
1:30 p.m. – 3:30 p.m.

State Capitol
Room 4202

Immunization: A Public Health Success Story

Vaccines are widely believed to be among the greatest public health achievements of the 20th century, having nearly eradicated diseases that previously infected hundreds of thousands of people and killed tens of thousands of people annually. Vaccines are cost-effective tools that prevent disability and death and control the spread of diseases within communities.[1] As one physician describes, vaccines have made a very visible difference in his lifetime:

> *Many of us recall that only two generations ago we had schoolmates who limped or had withered arms due to the paralytic polio they were infected with. That disease is now extinct in the U.S. because of the universal use of polio vaccine. During my training, I cared for children made deaf from measles, infants blind and retarded from rubella, and those who died from bacteria like pneumococcus and meningococcus. With vaccination, those conditions no longer occur. As a physician in my early years of practice, the threat of infection with bacteria called Haemophilus influenza type B (Hib) loomed large for my patients and their families, the outcomes of brain damage or death being distinct possibilities. A vaccine was invented, adopted as policy, and given to U.S. infants and children. I'm pleased to say I no longer worry about Hib infection.*[2]

The United States (U.S.) Centers for Disease Control and Prevention (CDC) notes that, through universal vaccination, some diseases, such as polio and diphtheria, have become very rare in the U.S.[3] Smallpox has been virtually eradicated worldwide[4] so there is no longer a need to immunize against it.[5] Even though most vaccine-preventable diseases have become far less common in the U.S., immunizations continue to be essential for the protection of public health.[6]

Immunization protects not just the person who receives the vaccine, but also the community. Immunized people are much less likely to transmit infections, protecting anyone who may not have been immunized. Sometimes referred to as "herd immunity," the broader public health protection which results from immunizations is particularly important in protecting people who cannot be effectively vaccinated for medical reasons or because they are too young, or for people who do not develop adequate immunity despite vaccination. In order to achieve herd immunity, approximately 95% of a community must be vaccinated.[7]

Vaccines have also been shown to save money. A 2005 national study showed that the seven childhood immunizations recommended by the federal Advisory Committee on Immunization Practices (ACIP) saved $9.9 billion in direct medical costs and $43.3 billion in societal costs annually.[8] Studies have also shown significant savings from the use of varicella (chickenpox), influenza (especially for persons over 65 years), pneumonia, pertussis, and meningitis vaccines.[9]

I. State Immunization Law and Programs

Mandatory Immunizations for School-Age Children

Existing California law reflects the importance of immunizations, stating the intent of the Legislature to provide "[a] means for the eventual achievement of total immunization of appropriate age groups against the following childhood diseases:"

1) Diphtheria;
2) Hepatitis B;
3) Haemophilus influenza type B (Hib);
4) Measles;
5) Mumps;
6) Pertussis (whooping cough);
7) Poliomyelitis;
8) Rubella;
9) Tetanus;
10) Varicella (chickenpox); and,
11) Other diseases as deemed appropriate by the California Department of Public Health (CDPH), ACIP, and the American Academy of Pediatrics (AAP) Committee of Infectious Diseases.[10]

Existing law prohibits the governing authority of a private or public elementary or secondary school, child care center, day nursery, nursery school, family day care home, or development center from unconditionally admitting any pupil unless he or she has been fully immunized against the ten diseases specified above, with age-specific exceptions for Hib and pertussis (whooping cough), and any other disease CDPH deems appropriate.[11]

Existing law establishes exemptions from the school and child care immunization requirements for specific medical reasons, and establishes a personal beliefs exemption (PBE), if the

immunization is contrary to the parent or guardian's beliefs. Any parent or guardian has the option to use the PBE at any time by signing an affidavit on the back of the child's School Immunization Record, or Blue Card, which must be kept in the student's official record.[12] In the event of a disease outbreak, the local health officers have statutory authority to order a school to temporarily exclude children who have not been immunized.[13] [14] [15]

The following medical exemptions are allowed:

1) A permanent medical exemption, if a child has a medical condition which permanently precludes one or more vaccines. A written statement from the child's physician is required;
2) A temporary medical exemption, if a child has a temporary medical condition which precludes one or more immunizations or the child's physician wishes to delay an immunization. A written statement from the child's physician, indicating which immunizations must be postponed, and for how long, is required; and,
3) An exemption for a child who has had measles, laboratory-confirmed rubella, laboratory-confirmed mumps, or chickenpox disease, documented by a physician, and only for immunizations against the disease the child already had.

State Monitoring and Oversight

The CDPH Immunization Branch provides leadership and support to public and private sector efforts to protect the population against vaccine-preventable diseases.[16] The Immunization Branch's activities include:

- Managing the state's Vaccines for Children Program (described below);
- Providing information to health care providers on various aspects of vaccine administration, including availability, storage, procurement, administration, and patient education, which includes bimonthly updates on the CDPH web site;
- Educating the public on immunizations, such as launching "i choose," a public education campaign featuring local advocates to promote the decision to get immunizations as a social norm; and,
- Collecting and publishing information on immunization compliance and vaccine-preventable diseases in California.[17]

California Immunization Registry (CAIR)

Existing law authorizes local health officers (LHO) to operate immunization information systems, or registries, in conjunction with the CDPH Immunization Branch, either separately within their individual jurisdictions, or jointly among more than one jurisdiction. Existing law also authorizes a patient's physician, the local health department (LHD), and CDPH to maintain access to immunization information for the purpose of patient care or protecting public health, and to share information with other states for families moving between states.[18]

Existing law authorizes health care providers and other specified agencies to share with CDPH and LHDs that are operating immunization registries the following information about a patient:

1) Name;
2) Date of birth;
3) Types and dates of immunizations received;
4) Manufacturer and lot number for each immunization received;
5) Adverse reaction to immunizations received;
6) Other nonmedical information necessary to establish unique identity and record;
7) Current address and telephone number;
8) Gender; and,
9) Place of birth.

CAIR, a public-private collaboration of nine regional registries and one county registry, serves as California's immunization information system. The goals of CAIR are to improve immunization rates for California children, ensure that health care providers have rapid access to complete and up-to-date immunization records, to eliminate missed opportunities to immunize and to avoid duplicate immunizations. All of California's LHDs participate in one of the regional or county registries, and provide information that is accessible by CDPH, but all of the registries are not electronically linked with each other. The ultimate goal of CAIR is to establish a statewide, computerized registry containing full immunization history for all California children.

CAIR captures and consolidates all of a child's immunization information from one or more health care providers into one place. Immunization records are entered into CAIR at the doctor's office or clinic. CAIR also generates reminder notices for patients' immunizations appointments to help health care providers keep their patients up-to-date.[19] Schools, child care facilities, and family child care homes, which must all verify that children have been fully immunized use CAIR, as do Women, Infants, and Children (WIC) nutrition program service providers, foster care agencies, welfare departments, juvenile justice facilities, and other programs that either provide or require immunizations.

Nationally, approximately 43% of children age six years and younger are enrolled in a registry. One of the U.S. Department of Health and Human Services' Healthy People 2010 national health objectives is to increase to 95% the proportion of children age six years and younger who participate (i.e., have two or more vaccinations recorded) in fully operational, population-based immunization registries. In 2002, four states had achieved the 95% participation goal. California was among the states reporting less than 33% participation.[20] In 2002, 37 states and the District of Columbia reported operating registries that target their entire geographic areas, while California and six other states operate local or regional registries that target only regions or counties within their geographic areas.[21]

California Kindergarten Immunization Rates

The CDPH Immunization Branch conducts the Kindergarten Retrospective Survey to estimate the percentage of children 24 months of age who had completed the 4:3:1 vaccine series, which is four or more doses of Tdap (tetanus, diphtheria, and pertussis), three or more doses of polio, and one or more doses of MMR (measles, mumps, rubella) immunizations. In 2007, the percent of kindergarteners who had completed the 4:3:1 vaccine series at 24 months was 77% among white children, 75% among Hispanic children, 72% among African American children, and 82% among Asian children. [22] The data indicate that California falls short of the Healthy People 2010 target of 90% for young children.[23] Other data on vaccination rates in California are not readily available.

II. Federal Law and Programs

Advisory Committee on Immunization Practices (ACIP)

Federal law requires the ACIP to provide advice and guidance to the Secretary of the U.S. Department of Health and Human Services, the Assistant Secretary for Health, and the CDC on the most effective means to prevent vaccine-preventable diseases. Another goal of ACIP is to increase the safe usage of vaccines and related biological products. ACIP consists of 15 experts in fields associated with immunization who have been selected by the Secretary, and is the only entity in the federal government which develops recommendations for the routine administration of vaccines to children and adults, along with schedules regarding the appropriate, dosage, dosing intervals, precautions, and contraindications applicable to the vaccines.

Vaccines for Children (VFC) Program

VFC provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. VFC was created by the federal Omnibus Budget Reconciliation Act of 1993 as a new entitlement program to be a required part of each state's Medicaid plan (Medi-Cal in California). Funding for VFC is allocated to the CDC, which buys vaccines at a discount and distributes them to state health departments and certain other public health agencies. States and local health departments then distribute the vaccines at no charge to private physicians' offices and public health clinics registered as VFC providers.[24] The VFC is administered by CDPH in California.

Any licensed physician or health care organization serving VFC-eligible children can become a VFC provider. To participate, a provider must submit an enrollment form to the Immunization Branch and commit to following standard procedures and guidelines, such as those of ACIP, and agree to Quality Assurance Reviews by a VFC field representative.

To be eligible to receive VFC vaccinations, children must be 18 years of age or younger and meet one of the following criteria:

1) Eligible for Medi-Cal or the Child Health and Disability Prevention Program;
2) Uninsured; or,
3) American Indian or Alaskan Native.

Additionally, children who have health insurance without immunization coverage may receive VFC vaccines, but only at federally qualified health centers (community clinics) or rural health clinics. Children enrolled in the Healthy Families Program (California's State Children's Health Insurance Program) are not VFC-eligible. [25] Under federal law, VFC providers may charge an administration fee that does not exceed the actual cost of administering the vaccine.[26] In California, the Medi-Cal administration fee is $9 per immunization for Medi-Cal eligible children.[27]

Immunization Grant Program (Section 317)

Section 317 of the federal Public Health Service Act was established in 1962 to provide funds to every state and some LHDs for mass immunization campaigns. Section 317 provides funding for vaccinations to uninsured children and adolescents not served by the VFC, and as funding permits, to uninsured and underinsured adults.[28] According to CDC, which administers the Section 317 immunization program, Section 317 remains the primary source of funding for most local vaccine program operations. CDPH administers the program in California to purchase vaccines and to support state immunization operations and LHD immunization programs.

III. Challenges and Opportunities

Restoring Confidence in Vaccines

Many people have become very wary of vaccines due to widely publicized reports that vaccines cause autism or other problems, despite the overwhelming science that refutes the supposed links. Parents also worry that their young children are required to receive too many vaccines when they are still too young. Pediatricians report having to spend a great deal of time assuring fearful parents that vaccinating their children is the right thing to do.[29] As noted earlier vaccines remain critical to public health and parents need to understand that serious vaccine-preventable diseases have not gone away. Additionally, vaccine safety research must continue to be a priority.

Personal Beliefs Exemption (PBE)

As more people have chosen to exercise the PBE,[30] outbreaks of vaccine-preventable diseases such as measles and pertussis have been occurring.[31] Schools with exemption rates of 2-4% are at increased risk of outbreaks. In California in 2008, 1.9% of kindergarten children statewide use the PBE, but the percentage varied widely among counties. There were eighteen counties with PBE rates over 4%. In Humboldt County, for instance, 10% of kindergarteners used the PBE and in Nevada County, over 14% used the PBE.[32] In a January 2008 outbreak in San Diego, an unvaccinated student who was exposed to measles in Switzerland returned to San Diego and

infected 11 other children, including two infants. One of the infants needed to be hospitalized and the other traveled by plane to Hawaii while infectious. Of the nine patients 12 months or older, eight had not been vaccinated due to PBEs.[33]

Disparities among Adults

Wide ethnic and racial disparities persist in vaccination rates among adults. Nationally, only 47% of African American and 45% of Hispanic adults over 65 years, compared with 67% of non-Hispanic whites, had received influenza vaccinations in 2006. For pneumonia, 36% of African Americans, 33% of Hispanics, and 62% of whites had been vaccinated. Pneumonia and influenza are significant causes of death in people 65 over years.[34]

Immunization Data and Registry

The California Performance Review, created by Governor Schwarzenegger in 2004 to examine state government and make recommendations to increase efficiency, included a recommendation to fully fund the state immunization registry "for the health and well-being of California's children and all other citizens..." The low level of participation in the state immunization registry is also a concern.

IV. Related and Previous Legislation

- AB 354 (Arambula) would remove specified age and date restrictions from the current list of vaccinations required for pupils before entering any private or public elementary or secondary school, child care center, day nursery, nursery school, family day care home, or development center.

- AB 977 (Skinner) would among other things, authorize a pharmacist to initiate and administer immunizations pursuant to a protocol with a prescriber or the recommended Immunization Schedules provided by CDC. In addition, the bill would require a pharmacist to maintain a specified immunization administration record, report any adverse event and administer epinephrine for severe allergic reactions, and assure proper storage and handling of vaccines.

- SB 249 (Cox) would authorize CDPH to include children 11 years of age in the public awareness campaign about meningococcal disease that the department is already authorized to design and implement.

- SB 158 (Wiggins) would require specified health plan contracts and insurance policies to provide coverage for the human papillomavirus vaccination (HPV), as specified.

- AB 2580 (Arambula) of 2008 would have required pupils entering the 7th grade to be fully immunized against pertussis by receiving any necessary adolescent booster immunization and would have deleted age-specific exemptions for school entry

requirements as they apply to the Hib, mumps, and pertussis vaccines. AB 2580 was held on the Senate Appropriations Committee suspense file.

- AB 16 (Evans) of 2008 would have required health plans and health insurers that currently provide coverage for cervical cancer to also cover the HPV vaccine. AB 16 was vetoed by Governor Schwarzenegger, who stated that the addition of a new mandate, no matter how small, would only serve to increase the overall cost of health care.

- SB 1179 (Aanestad) of 2008 would have removed from CDPH the authority to add immunizations to the current list that is required for admission to school so that only the Legislature could determine which immunizations are necessary. SB 1179 was scheduled to be heard in the Assembly Health Committee on April 10, 2008, but the hearing was cancelled at the request of the author.

- SB 676 (Ridley-Thomas) of 2007 would have prohibited a governing authority of any school board, or private or public educational institution, as specified in existing law, from unconditionally admitting or advancing any pupil to the seventh grade level, unless the pupil has been fully immunized against pertussis, including any necessary adolescent pertussis booster immunizations. SB 676 also would have allowed CDPH to add other vaccinations to the list of vaccinations required for school admission. SB 676 was held on the Assembly Appropriations Committee suspense file.

- SB 533 (Yee) of 2007 would have added pneumococcus vaccination for children under 24 months of age to the list of immunizations required prior to admission into schools, child care centers, nursery schools, day care, and development centers. The governor vetoed SB 533, stating: "The Department of Public Health can already require that young children receive the pneumococcal vaccine. California's vaccine experts have not established a mandate as they believe it is not needed. Approximately 86 percent of children are already being vaccinated under a voluntary system."

- AB 16 (Hernandez) of 2007 would have repealed and recast immunization statutes relating to school children and would have required children to be immunized in accordance with recommendations of the CDC upon approval by the State Public Health Officer. AB 16 was subsequently amended to address a different subject.

V. Conclusion

Immunizations may be a victim of their own success: Many people have forgotten -- or have never known -- how common many serious vaccine-preventable diseases were, and how frequently they resulted in disability and death. However, the need for immunizations has not diminished, and the challenges ahead will require continuing efforts in educating and reassuring the public, monitoring diseases, ensuring access to vaccines, and ensuring vaccine safety.

[1] Healthy States Partnership to Promote Public Health, "Immunization: A Prevention Strategy That Works."
[2] Richard G. Judelsohn, "Vaccine Safety: Vaccines Are One of Public Health's Great Accomplishments." *Skeptical Inquirer*, November/December 2007. http://www.csicop.org/si/2007-06/judelsohn.html
[3] http://www.cdc.gov/vaccines/vac-gen/why.htm
[4] http://www.bt.cdc.gov/agent/smallpox/overview/disease-facts.asp
[5] http://www.bt.cdc.gov/agent/smallpox/overview/disease-facts.asp
[6] http://www.cdc.gov/vaccines/vac-gen/why.htm
[7] Healthy States Partnership, "Immunization: A Prevention Strategy that Works."
[8] Fangjun Zhou, et al. Ecoomic Evaluation of the 7-Vaccine Routine Childhood Immunization Schedule in the United States, 2001. Arch Pediatr Adolesc Med. 2005;159:1136-1144.
[9] Healthy States Partnership to Promote Public Health, "Immunization: A Prevention Strategy That Works."
[10] California Health and Safety Code, Section 120325
[11] California Health and Safety Code, Section 120325
[12] California Department of Public Health, Immunization Branch, *California Immunization Handbook for Schools and Child Care Programs*, 7th Edition, July 2003.
[13] California Health and Safety Code, Division 105, Part 2, Chapter 1, Sections 120325-120380
[14] California School Immunization Law Exemptions Information Sheet http://www.cdph.ca.gov/programs/immunize/Documents/imm488e.pdf
[15] Code of Regulations, Title 17, Division 1, Chapter 4, Subchapter 8, 6000-6075.
[16] http://www.cdph.ca.gov/programs/immunize/Pages/AbouttheImmunzationBranch.aspx
[17] http://www.cdph.ca.gov/programs/immunize/Pages/VaccinePreventableDiseaseSurveillance.aspx
[18] California Health and Safety Code, Division 105, Part 2, Chapter 1, Section 120440
[19] Carol Fisher Stockman(?), Manager, California Immunization Registry, Sacramento Region. Testimony for Assembly Committee on Health Informational Hearing, March 3, 2009.
[20] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5320a3.htm
[21] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5320a3.htm
[22] http://www.cdph.ca.gov/PROGRAMS/IMMUNIZE/Pages/ImmunizationRateDisparities.aspx
[23] U.S. Department of Health and Human Services, Healthy People 2010 Objective 14-22.
[24] http://www.cdc.gov/vaccines/programs/vfc/default.htm
[25] How the VFC Program Works. http://www.eziz.org/pages/VFChoworks.html
[26] http://www.cdc.gov/vaccines/programs/vfc/projects/faqs-doc.htm#admfees
[27] Memorandum from Mark Horton, MD, Director, California Department of Public Health, in response to a request for information from Assemblymember Juan Arambula, dated August 11, 2008.
[28] Healthy States Partnership, "Immunization: A Prevention Strategy that Works."
[29] Louis Cooper, Heidi Larson, Samuel Katz, "The Confidence Gap." Newsweek.com; http://newsweek.coom/id/185986.
[30] Jill Adams, "Contagious disease's spread highlights dilemma over unvaccinated kids." Los Angeles Times February 23, 2009.
[31] Healthy States Partnership, "Immunization: A Prevention Strategy that Works."
[32] California Department of Public Health, Immunization Branch, 2008 Kindergarten Assessment Results.
[33] CDC, "Outbreak of Measles – San Diego, California – January-February 2008. MMWR February 22, 2008/57 (Early Release); 1-4.
[34] Healthy States Partnership, "Increasing Vaccination Rates in Adults." December 2007.